

Patent Claims

- 1) A composition comprising tiotropium, or a pharmaceutically acceptable salt thereof, salmeterol xinafoate, and a physiologically acceptable excipient.
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- 2) The composition according to claim 1 comprising tiotropium in combination with a counter-ion selected from among the chloride, bromide, iodide, methanesulphonate or para-toluenesulphonate thereof.
- 10 3) The composition according to claim 1 wherein the salmeterol xinafoate comprises the characteristic values $d = 21.5 \text{ \AA}$; 8.41 \AA ; 5.14 \AA ; 4.35 \AA ; 4.01 \AA and 3.63 \AA in an X-ray powder diagram.
- 4) The composition according to claim 1 wherein the salmeterol xinafoate has a
15 compacted bulk volume of $\geq 0.134 \text{ g/cm}^3$.
- 5) The composition according to claim 1 comprising salmeterol xinafoate in an amount of 0.002 to 15%.
- 20 6) The composition according to claim 1 comprising tiotropium in an amount of 0.001 to 5%.
- 7) The composition according to claim 1 comprising tiotropium and salmeterol xinafoate in a combined amount of from 5 to $5000 \mu\text{g}$.
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- 8) The composition according to claim 1 comprising a physiologically acceptable excipient selected from the group consisting of monosaccharides, disaccharides, oligo- and polysaccharides, polyalcohols and salts.

- 9) The composition according to claim 8 wherein the physiologically acceptable excipient is selected from among glucose, arabinose, lactose, saccharose, maltose and trehalose, optionally in the form of the hydrates thereof.
- 5 10) The composition according to claim 1 wherein the salmeterol xinafoate has a melting point of about 124°C.
- 11) A capsule comprising the composition according to claim 1.
- 10 12) The capsule according to claim 11 comprising 1 to 20mg of the composition.
- 13) The capsule according to claim 12 comprising 4 to 6mg of the composition.
- 14) The capsule according to claim 12 comprising 8 to 12mg of the composition.
- 15 15) An inhalation kit comprising the capsule according to claim 11 and an inhaler.
- 16) The inhalation kit according to claim 15 wherein the inhaler comprises a housing comprising two windows, a deck in which there are air inlet ports and which is provided
20 with a screen secured via a screen housing, an inhalation chamber connected to the deck on which there is a push button provided with two sharpened pins and movable counter to a spring, and a mouthpiece which is connected to the housing, the deck and a cover via a spindle to enable it to open or shut, and airholes for adjusting the flow resistance.
- 25 17) The composition according to claim 1 in the form of an inhalable powder.
- 18) The composition according to claim 2 in the form of an inhalable powder.
- 19) The composition according to claim 5 in the form of an inhalable powder.
- 30 20) The composition according to claim 6 in the form of an inhalable powder.